IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

DORIS JACKSON, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.	CIVIL ACTION FILE NO. 1:11-CV-3903-TWT

OPINION AND ORDER

This is a products liability case on remand from multidistrict litigation proceedings. It is before the Court on a number of *Daubert* motions by the Parties. For the reasons set forth below, the Court rules as follows:

- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Sepulveda-Toro [Doc. 52] is DENIED.
- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Schlafstein [Doc. 53] is DENIED.
- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Thames [Doc. 54] is DENIED.
- The Plaintiff's Unopposed Motion for Extension of Time [Doc. 72] is GRANTED.
- The Defendants' Motion to Exclude Certain Case Specific Opinions of Dr. Fitzgerald [Doc. 55] is GRANTED.
- The Defendants' Motion to Limit the Expert Opinions of Dr. Elliott [Doc. 56] is GRANTED in part and DENIED in part.

- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Lowman [Doc. 58] is DENIED.
- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Rosenblatt [Doc. 59] is DENIED.
- The Plaintiff's Motion to Exclude Timothy Ulatowski [Doc. 60] is GRANTED.
- The Defendants' Motion to Exclude the Case-Specific Opinions of Dr. Miklos [Doc. 61] is GRANTED.
- The Defendants' Motion to Exclude the Case-Specific Opinions of Dr. Zipper [Doc. 89] is DENIED.
- The Defendants' Motion to Exclude Certain Opinions and Testimony of Prof. Dr. Uwe Klinge [Doc. 90] is GRANTED in part and DENIED in part.

I. Background

This case is one of many that were consolidated in MDL 2327 in the United States District Court for the Southern District of West Virginia. (Jan. 21, 2020 Order, at 1, 3.) The Plaintiff, Doris Jackson, suffered from pelvic organ prolapse. (Compl. ¶ 23.) To treat this condition, the Plaintiff received a Prolift Anterior and Posterior Pelvic Floor Repair System ("Prolift"), which was designed, manufactured, and distributed by the Defendants, Johnson & Johnson ("J&J") and Ethicon, Inc. ("Ethicon"). (*Id.* ¶¶ 5, 9, 23.) The Plaintiff alleges that as a result the Prolift implantation, she has suffered a variety of physical, emotional, and financial injuries. (*Id.* ¶ 25.) Consolidated and coordinated proceedings were completed in the MDL and the case was

remanded to this district for trial. Both parties have identified numerous experts, and these experts now face the *Daubert* challenges detailed below.

II. Legal Standard

"Under Federal Rule of Evidence 702, expert testimony is admissible if (1) the expert is qualified to testify regarding the subject of the testimony; (2) the expert's methodology is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the expert's testimony will assist the trier of fact in understanding the evidence or determining a fact at issue." *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1304 (11th Cir. 2014). The Rules of Evidence require a district judge to undertake a gatekeeping function to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrill Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993). "In considering the proffered expert testimony, a trial judge is mindful the burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion." *Chapman*, 766 F.3d at 1304 (internal quotation marks and punctuation omitted).

III. Discussion

The Court has reviewed the eleven *Daubert* motions pending before the Court and the underlying materials. Some of these experts were the subject of earlier *Daubert* motions before the MDL court, and where appropriate, the Court adopts Judge Goodwin's rulings. However, Judge Goodwin reserved

ruling on some issues, allowing this Court to assess these challenges on remand under Georgia law. Before evaluating the parties' motions, the Court pauses to make a general note. Federal Rule of Civil Procedure 26(a) and (e) require the disclosure of all bases of expert opinions. The experts in this case are limited to these bases and the contents of their expert reports, and the Court will decide these motions based on this information. To the extent the experts provide testimony outside the scope of their reports, the opposing party may renew their objections at the time the testimony is offerred. *See, e.g.*, *Mitchell v. Ford Motor Co.*, 318 F. App'x 821, 824–25 (11th Cir. 2009) (affirming the district court's decision to strike additional bases for expert opinion outside of the scope of the Rule 26 disclosures.) The Court now begins with the Plaintiff's experts.

A. The Plaintiff's Experts

i. Dr. Miklos

Dr. John Miklos is a board-certified OB/GYN with expertise in female pelvic medicine and reconstructive surgery. (Dr. Miklos Report, at 2.) Along with his partner, Dr. Miklos performs approximately 450 pelvic floor reconstruction surgeries annually. (*Id.* at 5.) In his report, Dr. Miklos reviews the Plaintiff's medical history and his independent medical examination of the Plaintiff. (*Id.* at 7–15.) Dr. Miklos then conducts what he deems a differential diagnosis—a procedure for determining the root cause of a condition by "ruling in" potential causes and then "ruling out" possibilities until one cause remains.

(*Id.* at 15.) In his medical opinion, Dr. Miklos opines that the Plaintiff's "continued vaginal pain, levator myalgia, dyspareunia, shortened vagina and chronic vaginal discharge [are] a direct result of Gynecare Prolift mesh." (*Id.* at 19.) In their Motion to Exclude Dr. Miklos, the Defendants raise several arguments against the admission of his specific causation opinion. As relevant here, the Defendants argue that Dr. Miklos conducted an unreliable differential diagnosis by failing to rule in a different mesh implantation, and as such, his testimony fails to satisfy Rule 702. (Defs.' Br. in Supp. of Defs.' Mot. to Exclude Dr. Miklos, at 8–15.) In response, the Plaintiff points to Dr. Miklos' deposition testimony to explain how he ruled out the other mesh implantation and other alternative causes. (Pl.'s Br. in Opp'n to Defs.' Mot. to Exclude Dr. Miklos, at 9–13.)[1]

"When properly conducted, a differential diagnosis can be a reliable methodology under *Daubert*." *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010). An expert completes a differential diagnosis in three steps: first, diagnosing a patient's condition; second, ruling in all possible causes; and third, ruling out possible causes until one remains. *See Chapman*, 766 F.3d at 1308. In giving his medical opinion here, Dr. Miklos asserts that he has conducted a differential diagnosis. (Dr. Miklos Report, at 15.) However, an expert's mere statement that he conducted a differential diagnosis does not

[1] The Plaintiff concedes that Dr. Miklos will not testify as to her stress urinary incontinence, and the Defendants' Motion is granted as to this issue.

alone demonstrate the process' reliability, and courts must evaluate the expert's methodology before admitting the testimony. *Guinn*, 602 F.3d at 1253. "Although a reliable differential diagnosis need not rule out all possible alternative causes, it must at least consider other factors that could have been the sole cause of the plaintiff's injury." *Id.* The Eleventh Circuit, in joining several sister circuits, noted that "an expert must provide a reasonable explanation as to why he or she has concluded that any alternative cause suggested by the defense was not the sole cause of the plaintiff's injury." *Id.* (internal quotation marks and punctuation omitted).

Dr. Miklos conducted an independent medical exam of the Plaintiff, in which he diagnosed her with "chronic postoperative surgical pain, dyspareunia, levator myalgia, . . . shortened vagina," and other conditions. (Miklos Report, at 14.) Thus, Dr. Miklos successfully completed the first step of a reliable differential diagnosis. However, in his report, Dr. Miklos fails to rule in or out both the Plaintiff's 2007 vaginal hysterectomy and implantation of a different mesh product, Pelvitex, as potential causes of the Plaintiff's conditions. Dr. Miklos' review of the Plaintiff's medical history involves three gynecologic surgeries: the Prolift implantation in October 2006; a vaginal hysterectomy and Pelvitex implantation in May 2007; and a third surgery in 2010 consisting of, among other things, a lysis of adhesions and a vaginal cuff revision. (*Id.* at 8–10.) In detailing his medical opinion, Dr. Miklos "first ruled in the mesh as a potential cause because of the obvious timing, location and

presentation of the symptoms after the mesh placement." (*Id.* at 18.) Dr. Miklos then rules out the Plaintiff's "only preexisting condition" of gastroesophageal reflux (*Id.* at 7, 18.) At no point does Dr. Miklos rule in the Pelvitex mesh or the hysterectomy, instead stating that her pain was "diagnostic of a complication specific to a transvaginal mesh implant and in this case the [Prolift.]" (*Id.* at 18.) By failing to discuss the effect of the other surgical procedures performed on the Plaintiff and ruling out those surgeries as possible causes of her pain, Dr. Miklos fails to conduct a proper differential diagnosis, and his testimony is thus unreliable under *Daubert*.

The Plaintiff's brief points to deposition testimony that provides some explanation for why Dr. Miklos determined that the Prolift alone led to the Plaintiff's condition. For example, in his deposition, Dr. Miklos notes that if the Pelvitex alone was responsible for the pain, it would be limited to the upper part of the Plaintiff's vagina and not present throughout, as he has found. (*See* Dr. Miklos Dep., at 72:19–74:22.) However, regardless of the substance or persuasiveness of Dr. Miklos' explanations, subsequent deposition testimony cannot resuscitate an otherwise deficient expert report. As the Seventh Circuit has persuasively noted, Federal Rule of Civil Procedure 26(a)(2) "does not allow parties to cure deficient expert reports by supplementing them with later deposition testimony[:]"

> The purpose of Rule 26(a)(2) is to provide notice to opposing counsel—before the deposition—as to what the expert witness will testify, and this purpose would be completely undermined if

> parties were allowed to cure deficient reports with later deposition testimony. Allowing parties to cure a deficient report with later depositions would further undermine a primary goal of Rule 26(a)(2): to shorten or decrease the need for expert depositions. After all, the parties' need for expert depositions would increase if they could use deposition testimony to provide information they should have initially included in their Rule 26(a)(2) report.

Ciomber v. Coop. Plus, Inc., 527 F.3d 635, 642 (7th Cir. 2008). Because Dr. Miklos' report fails to demonstrate a reliable differential diagnosis, his testimony regarding the cause of the Plaintiff's condition is excluded.

ii. Dr. Fitzgerald

Dr. Colleen Fitzgerald is board-certified physician who specializes in, among other things, "women's pelvic and musculoskeletal rehabilitation[.]" (Dr. Fitzgerald Report, at 1.) Her expert report suffers from similar deficiencies as Dr. Miklos' report. In it, Dr. Fitzgerald states that she has conducted a differential diagnosis but does not specify the possible causes she ruled in and her reasons for ruling those causes out. (*Id.*, at 4.) The Eleventh Circuit has noted that "an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient." *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253 (11th Cir. 2005). Thus, this Court must evaluate Dr. Fitzgerald's methodology as described in her report. After summarizing the Plaintiff's medical history and records, Dr. Fitzgerald states that her medical opinion is that the Plaintiff's symptoms are "a result of vaginal mesh complications." (*Id.* at 16.)

In addition to not ruling in or out other potential causes, Dr. Fitzgerald fails to distinguish between the two mesh products implanted in the Plaintiff and does not rule out the other surgeries as a potential cause of the symptoms. As a result, Dr. Fitzgerald's differential diagnosis is unreliable under *Daubert*.

In responding to the Defendants' arguments that Dr. Fitzgerald's differential diagnosis is unreliable, the Plaintiff makes two arguments in support of admitting Dr. Fitzgerald's specific causation testimony. First, the Plaintiff points to extensive comments made during Dr. Fitzgerald's deposition explaining her thought process. (Pl.'s Br. in Opp'n to Defs.' Mot. to Exclude Dr. Fitzgerald, at 5–11.) As discussed above, deposition testimony cannot cure a deficient expert report. Second, the Plaintiff argues that Judge Goodwin, who presided over the MDL proceedings in this case, previously admitted Dr. Fitzgerald's specific causation testimony based on a differential diagnosis in a similar case. (*Id.* at 7 (citing *Wise v. C.R. Bard, Inc.*, 2015 WL 521202, at *12 (S.D. W. Va. Feb. 7, 2015)).) However, the MDL Court noted that Dr. Fitzgerald's report in that case "include[d] a section ruling out other causes of pain, such as endometriosis and kidney stones." *Wise*, 2015 WL 521202, at *12. No such section exists in Dr. Fitzgerald's report here. As a result, Dr. Fitzgerald's specific causation testimony as to both the Plaintiff's pelvic pain and urinary incontinence is excluded.

iii. Dr. Elliott

Dr. Elliott is a Professor of Urology specializing in female urology and reconstructive surgery. (Elliott Report, at 1.) The MDL court previously issued a ruling on the Defendant's Motion to Exclude Certain General Opinions of Dr. Elliott, in which Judge Goodwin ruled on some matters and reserved ruling on others. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500766 (S.D. W. Va. Aug. 26, 2016). Where the MDL court made definitive rulings on the Defendants' motion, this Court adopts those rulings for the reasons given in its Order. *See id.* The MDL court reserved ruling on several matters: whether Dr. Elliott can opine on alternative procedures that may be safter that the Defendants' products; and whether Dr. Elliott can opine on alternative designs. *Id.* at 4.

Regarding testimony on alternative procedures, the Defendants argue that Dr. Elliott's testimony regarding the availability of other procedures is irrelevant to the design concept and features of the products here. (Defs.' Br. in Supp. of Defs.' Mot. to Exclude Dr. Elliott, at 4.) The Defendants point to subsequent rulings on this issue by Judge Goodwin and other cases under Georgia law to support the notion that alternative procedures go to the treating physician's choice of product rather than the design of the product in question. (*Id.* at 4–7.) In response, the Plaintiff claims that the availability of alternative products and procedures "is highly relevant to whether it was negligent for Ethicon to put its Prolift onto the market[,]" and that Dr. Elliott's experience allows him to provide reliable testimony regarding alternative mesh designs.

(Pl.'s Br. in Opp'n to Defs.' Mot. to Exclude Dr. Elliott, at 7, 11.) Further, the Plaintiff urges this Court to adopt the reasoning of *Williams v. Ethicon, Inc.*, 2021 WL 1087808 (M.D. Ga. Mar. 22, 2021), in which the court applied Georgia law and denied Ethicon's motion to exclude Dr. Elliott's opinions regarding both alternative designs and procedures. (*Id.* at 5.)

Under Georgia law, design defect claims are subject to the risk-utility analysis outlined in *Banks v. ICI Americas, Inc.*, 264 Ga. 732, 736 n.6 (1994). When considering alternative safe designs, the Georgia Supreme Court provides the following non-exhaustive list of factors in the risk-utility analysis:

> [T]he feasibility of an alternative design; the availability of an effective substitute for the product which meets the same need but is safer; the financial cost of the improved design; and the adverse effects from the alternative.

Id. Thus, Georgia law allows consideration of both alternative product designs and alternative procedures—in the Supreme Court's words, effective substitutes—in evaluating a design defect claim. The Defendants argue that "effective substitute" represents a "substitute product design," and the proper analysis remains limited to alternative designs rather than alternative procedures. (Defs.' Reply Br. in Supp. of Defs.' Mot. to Exclude Dr. Elliott, at 5.) But defining "effective substitute" as a substitute product design renders this factor surplusage, as consideration of an "alternative design" is already included in the analysis. *Banks*, 264 Ga. at 736 n.6. Dr. Elliott is qualified to discuss these alternative procedures given his robust experience in female

pelvic surgery. (Elliott Rep., at 1.) As a result, the Defendants' Motion is denied as to this issue, and Dr. Elliott may testify as to alternative procedures.

Regarding alternative mesh designs, the MDL court found that Dr. Elliott was qualified to opine on alternative designs but reserved ruling on the reliability of Dr. Elliott's methodology. *In re: Ethicon, Inc.*, 2016 WL 4500766, at *4 (S.D.W. Va. Aug. 26, 2016). Further, the MDL court noted the contrasting arguments regarding Dr. Elliott's sources: the Defendants argued that the underlying sources did not support his conclusions, while the Plaintiff argued that Dr. Elliott explained his rationale for relying on those reports. *Id.* As a result, the MDL Court found that "the lynchpin of Dr. Elliott's testimony is his experience[,]" which Judge Goodwin reserved ruling on. *Id.* The Defendants make three arguments against the reliability of Dr. Elliott's testimony: first, they argue that he opposes the placement of any mesh in the vagina and acknowledged studies evaluating lighter products show no difference in complication frequency; that the medical literature does not support his opinions; and that his opinion is not supported by his personal experience. (Defs.' Br. in Supp. of Defs.' Mot. to Exclude Dr. Elliott, at 7–15.) The Court agrees with the Plaintiff that the Defendants' first two challenges above raise issues best handled by the "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Daubert*, 509 U.S. at 596. The Defendants' third arguments requires more analysis. As the Defendants note, when an expert relies on his

experience to support the reliability of his claims, the expert "must explain *how* that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *United States v. Frazier*, 387 F.3d 1244, 1261 (11th Cir. 2004). Dr. Elliott fails to describe any particular methodology, but instead uses his experience in the field to read and summarize the findings of medical literature. While this evidence may be "shaky," Dr. Elliott is qualified as an expert and has identified the sources supporting his opinion. *Daubert*, 509 U.S. at 596; *see also Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1345 (11th Cir. 2003) ("The identification of such flaws in generally reliable scientific evidence is precisely the role of cross-examination."). The Defendants have raised arguments against Dr. Elliott's conclusions, and the Court finds that the jury is well-placed to assess those arguments. As such, the Defendants' Motion is denied as to Dr. Elliott's testimony on alternative design features.

As a final matter regarding Dr. Elliott, the Defendants ask this Court to exclude any testimony regarding "certain duties owed by a medical device manufacturer." (Defs.' Br. in Supp. of Defs.' Mot. to Exclude Dr. Elliott, at 15.) The Plaintiff, in response, argues that Dr. Elliott "plans to testify not on the legal adequacy of Ethicon's testing, but rather on whether the clinical studies, testing and the factual circumstances dictated that additional, longer-term

testing was needed to ensure the safety and efficacy of the Prolift before bringing it to market." (Pl.'s Br. in Opp'n to Def.'s Mot. to Exclude Dr. Elliott, at 12.) As other courts have found, the "Plaintiff's distinction is not persuasive." *Mason v. Ethicon, Inc.*, 2021 WL 2580165, at *5 (M.D. Fla. Jun. 10, 2021). While Dr. Elliott can testify as to factual matters such as whether or not certain testing or studies took place based on the information available to him, he cannot testify as to the sufficiency of those efforts, and the Defendants' Motion is granted as to this issue. Further, Dr. Elliott can testify as to the Prolift's instructions for use as limited in Judge Goodwin's Order on this issue. (*See* Def.'s Mot. to Exclude Dr. Elliott, Ex. 2 [Doc. 56-3], at 2.) Thus, the Defendant's Motion to Exclude Dr. Elliott is granted in part and denied in part.

iv. Dr. Zipper

Dr. Zipper is a board-certified surgeon specializing in female pelvic medicine and reconstructive surgery and has "performed over one thousand mesh and biologic tissue implantations, pelvic organ prolapse procedures, and a similar numbers of native tissue prolapse surgeries." (Dr. Zipper Report, at 3.) The MDL court previously ruled on some of the Defendants' challenges to Dr. Zipper's testimony, and the Court adopts that opinion as its own here. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4944991 (S.D. W. Va. Sept. 1, 2016). Judge Goodwin reserved ruling on Dr. Zipper's testimony regarding the existence of alternative designs and procedures. *Id.* at *2–3. As they did in challenging Dr. Elliott's testimony, the Defendants argue

that (1) the availability of alternative surgeries is irrelevant to any potential design defects in the Prolift and (2) that Dr. Zipper fails to utilize a reliable methodology in developing his opinion on alternative designs. (Defs.' Br. in Supp. of Defs.' Mot. to Exclude Dr. Zipper, at 4–10.) In response, the Plaintiff claims that Dr. Zipper's opinion rests on his expertise and studies he reviewed comparing the complications of various mesh products.

The Court sees no reason to deviate from its reasoning in evaluating the Defendants' challenge to Dr. Elliott. As discussed above, one factor to consider in design defect cases under *Banks* is the availability of other procedures that could achieve the same results with fewer risks. *See Banks,* 264 Ga. at 736 n.6. The Defendants highlight *Jones v. NordicTrack, Inc.*, 274 Ga. 115, 118 (2001), arguing that the Georgia Supreme Court's decision in that case emphasizes "the significance of proof of a safer alternative ***design*** establishing a design defect claim." (Defs.' Reply Br. in Supp. of Defs.' Mot. to Exclude Dr. Zipper, at 2.) But the Georgia Supreme Court's ruling in *Jones* does not discount the importance of evidence of a reasonable alternative design by also allowing consideration of effective substitute procedures in accordance with *Banks*. Because this evidence is relevant to the Plaintiff's design defect claim, the Court can evaluate Dr. Zipper's qualifications and his methodology. Dr. Zipper has performed hundreds of pelvic surgeries and is thus qualified to talk about his general opinion regarding the comparative efficacy and safety of these procedures, and his experience and study in this field represents a sufficiently

reliable basis for his opinions. (Dr. Zipper Report, at 3–21.) Regarding alternative designs, Dr. Zipper has based his opinion on a review of studies on these products. (*Id.* at 175–178.) After a review of these studies, Dr. Zipper opines that the Prolift is "more defective than other commercially available meshes." (*Id.* at 178.) The Defendants' arguments amount to an attack on the sufficiency of the medical literature undergirding his opinions, and the "identification of such flaws in generally reliable scientific evidence is precisely the role of cross-examination." *Quiet Tech. DC-8, Inc.*, 326 F.3d at 1345. As such, the Defendants' Motion to Exclude Dr. Zipper's testimony on these points is denied.

v. Prof. Dr. Med. Klinge

Dr. Uwe Klinge is hernia surgeon who has utilized similar mesh products in hernia surgeries outside of the pelvic organ prolapse or stress urinary incontinence context. (Dr. Klinge Report, at 1.) As a researcher, Dr. Klinge's work on hernia meshes was supported by Ethicon and later became part of an Ethicon product. (*Id.* at 2.) As a surgeon and researcher involved in the development of surgical meshes, even outside the specific context of pelvic organ prolapse, Dr. Klinge is qualified to offer his opinion here.

The Court now turns to the reliability of his proposed testimony.[2] The Defendants make several arguments that this Court should exclude Dr.

2 The Plaintiff concedes that they will abide by the MDL court's ruling excluding Dr. Klinge's opinions as to the Defendants' knowledge or state of

Klinge's testimony regarding alternative designs. In particular, the Defendants argue that: (1) the alternative mesh product referenced by Dr. Klinge—PVDF—was not on the market when the Plaintiff received her Prolift implantation; (2) Dr. Klinge's opinion is not based on scientific literature; (3) Dr. Klinge's opinion is speculative for lack of sufficient testing and data; and (4) that his testimony does not fit the facts of the case here, as the case-specific experts did not suggest Dr. Klinge's suggested alternatives could be used. (Defs.' Br. in Supp. of Defs.' Mot. to Exclude Dr. Klinge at 2–10, 11–12.) The Court finds the Defendants' first and fourth arguments unpersuasive. First, whether or not the PVDF mesh was commercially available at the time of the Plaintiff's surgery does not bear on the "feasibility of a safer an equally efficacious design[.]" *Banks*, 264 Ga. at 735. Further, the Defendants' contention that such alternative products could not have lessened the Plaintiff's injuries are matters best-suited for the cross-examinations of Dr. Klinge and any of the Plaintiff's case-specific experts.

However, the Defendants' other arguments are more convincing. In particular, after the Defendants claimed that Dr. Klinge's opinion's on PVDF are not supported by testing or the scientific literature, the Plaintiff appears to cite a report by Dr. Klinge from a different case, referencing a statement on page 37 of a 32-page document. (*See* Pl.'s Br. in Opp'n to Def.'s Mot. to Exclude

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mind. (Pl.'s Br. in Opp'n to Defs.' Mot. to Exclude Dr. Klinge, at 19–20.)

Dr. Klinge, at 9.) In fact, the only statement of Dr. Klinge's that appears to have basis in a scientific study is the statement that Ethicon's PVDF mesh experienced less degradation than those made of polypropylene. (Dr. Klinge Report, at 18–19.) Given Dr. Klinge's experience, he seems to argue that polypropylene mesh undergoes more degradation and creates more of an inflammatory response. (*Id.* at 19.) Because this is the only opinion regarding PVDF with reference to scientific studies, this is the extent to which Dr. Klinge can compare the Defendants' product at issue with PVDF alternatives. Regarding his opinions comparing the Prolift with the Ultrapro product, the Plaintiff again cites Dr. Klinge's opinions that do not appear in his report for this case. (*See* Pl.'s Br. in Opp'n to Def.'s Mot. to Exclude Dr. Klinge, at 14.) The report includes no statement explicitly opining on Ultrapro's safety in comparison to Prolift, and references to depositions of other scientists or internal documents are not sufficiently reliable under *Daubert* in this context. Given these deficiencies, any testimony explicitly comparing the relative safety of Ultrapro to Prolift is excluded. *See Mason*, 2021 WL 2580165, at *5 ("While Dr. Klinge generally discusses what Ethicon knew about Ultrapro mesh, he does not opine Ultrapro mesh is a safer alternative.").

Finally, the Defendants seek to exclude Dr. Klinge's testimony regarding mesh fraying and particle loss, largely attacking the sufficiency of the data underlying his opinion. (Defs.' Br. in Supp. of Defs.' Mot. to Exclude Dr. Klinge, at 13–16.) As an example, Dr. Klinge discusses in his report that a

different type of mesh has an unsealed edge with frayed edges that can harm patients. (Dr. Klinge Report, at 22–23.) However, the Defendants fault Dr. Klinge for failing to cite any studies showing the Prolift's mesh is subject to fraying. (Defs. Reply Br. in Supp of Defs.' Mot. to Exclude, at 11.) These are disputes better settled through testimony and cross-examination. Dr. Klinge's report has a sufficiently reliable discussion of potential fraying and the harms associated with that fraying. (Dr. Klinge Report, at 14–15, 19–23.) The Defendants can raise these challenges to his testimony and his extrapolation from other meshes on the stand. Thus, the Defendants' Motion to Exclude Dr. Klinge is granted in part and denied in part.

B. The Defendants' Experts

The Plaintiff has filed six *Daubert* motions against the Defendants' proposed experts. Five of these experts are "general experts," and one is an alternative general expert offering testimony on the procedures and policies of the Food and Drug Administration and industry best practices. As with the Defendants' Motions, the Court will adopt prior rulings of the MDL court where appropriate.

i. Dr. Sepulveda-Toro

Dr. Jaime Sepulveda-Toro is a board-certified OB/GYN who specializes in female pelvic medicine and reconstructive surgery. (Dr. Sepulveda-Toro Report, at 1.) The MDL court previously ruled on a Motion to Exclude Dr. Sepulveda-Toro by the Plaintiff, and she asks this Court to adopt that ruling.

(Pl.'s Mot. to Exclude Dr. Sepulveda-Toro, Ex. B; *id.* at 1–2.) The Defendants claim that "despite asking this Court to adopt the MDL Court's rulings in this case, Plaintiff ignores certain of those rulings and simply reasserts the exact arguments made by MDL Plaintiffs that the MDL Court rejected." (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Sepulveda-Toro, at 3.) The Plaintiff does appear to raise challenges already decided by the MDL court. For example, Judge Goodwin ruled that Dr. Sepulveda-Toro could testify about the forces experienced by explanted mesh. (Pl.'s Mot. to Exclude Dr. Sepulveda-Toro, Ex. B, at 9.) However, the Plaintiff seeks to have this testimony excluded. (*Id.* at 6.) After review, this Court adopts the well-reasoned rulings of Judge Goodwin as its own. However, the Court provides one clarification. Judge Goodwin denied the Plaintiff's challenge as it related to Dr. Sepulveda-Toro's design opinions, finding that his report did not express "any opinions about the process of designing a product." (*Id.*, Ex. B, at 7.) Here, it appears the Plaintiff seeks to exclude Dr. Sepulveda-Toro's opinion as to the adequacy of the pelvic organ prolapse products' designs because he "is not a biomedical engineer[,] nor did he play any role in the design of the medical devices at issue." (*Id.* at 4.) Though he is not a biomedical engineer, he is a physician with deep experience using these devices. Insofar as his Report includes opinions regarding the product's design and defects, these references are supported by peer-reviewed studies and his own experience. (*See* Dr. Sepulveda-Toro Report, at 15, 18.) Thus, Dr. Sepulveda-Toro can opine on the design and lack of defects from his

experience. However, the Court reminds the parties that the experts' testimonies are limited to the confines of their reports, and subsequent challenges may be made to testimony as to matters not discussed in the Report.

Judge Goodwin reserved ruling on Dr. Sepulveda-Toro's proposed testimony regarding the adequacy of Ethicon's product brochures. (Pl.'s Mot. to Exclude Dr. Sepulveda-Toro, Ex. B, at 8–9.) The Plaintiff faults Dr. Sepulveda-Toro for lacking experience in drafting these types of brochures. (*Id.* at 5–6.) But that experience is unnecessary to describe his understanding of potential risks and defects associated with the Defendants' products and determine whether the brochures address those risks. As such, the Plaintiff's Motion is denied as to this issue.[3]

ii. Dr. Schlafstein

Dr. Barry Schlafstein is an OB/GYN specializing in female pelvic medicine and reconstructive surgery. (Dr. Schlafstein Report, at 2.) In addition to his practice, Dr. Schlafstein also serves as a Clinical Assistant Professor at the Medical College of Georgia. (*Id.*) He has deep experience utilizing both surgical and non-surgical interventions in treating pelvic organ prolapse. (*Id.*

[3] Judge Goodwin reserved ruling on two other issues in a section he entitled "Recurring Issues" and included in many other *Daubert* rulings. (Pl.'s Mot. to Exclude Dr. Sepulveda-Toro, Ex. B, at 12–13.) Because those issues appear irrelevant here, any challenge on those grounds is denied as moot. Where the issues described in Judge Goodwin's "Recurring Issues" section are not explicitly raised with regards to the experts in these proceedings, the Court denies those challenges as moot. Should those issues recur in the course of these proceedings, the parties may raise challenges addressing those issues.

at 3.) As with Dr. Sepulveda-Toro, the Plaintiff notes Judge Goodwin's previous *Daubert* ruling with regards to Dr. Schlafstein's testimony and asks this Court to adopt that order. (Pl.'s Mot. to Exclude Dr. Schlafstein, at 1–2.) Further, the Plaintiff asks this Court to exclude "any opinions related to design of the subject products" offered by Dr. Schlafstein. (*Id.* at 5.) The Defendants also ask this Court to adopt the MDL court's previous *Daubert* ruling on Dr. Schlafstein and argue that Judge Goodwin's ruling already settled the scope of Dr. Schlafstein's opinions related "to the clinical risks and benefits of these products[.]" (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Schlafstein, at 2–4.)

After review, the Court adopts Judge Goodwin's well-reasoned *Daubert* ruling as to Dr. Schlafstein. This Court shares Judge Goodwin's confusion as to the Plaintiff's definition of "design opinions," as the Plaintiff does not specify what types of design opinions she seeks to exclude. The Defendants note that "Dr. Schlafstein's opinions go to the clinical safety and effectiveness of Prolift." (*Id.* at 4.) In his report, Dr. Schlafstein does offer opinions as to potential flaws in the mesh's properties and bases these opinions on his clinical experience. (Dr. Schlafstein Report, at 19.) To the extent the Plaintiff challenges these opinions, her motion is denied. As a physician and professor, Dr. Schlafstein's experience is sufficiently reliable to allow him to testify as to the clinical risks and benefits of using Prolift and his understanding of the scientific literature on the topic. As he notes in his report, he "does not profess to be an expert in"

product design, and he does not appear to offer opinions based on factors outside of his clinical experience and review of the scientific literature on these devices. If his testimony escapes the boundaries of his report and relevant experience, the Plaintiff may raise a subsequent challenge to that testimony. Until such a time, the Plaintiff's Motion to Exclude Dr. Schlafstein is denied.

iii. Dr. Thames

Dr. Shelby Thames is a polymer chemist offered by the Defendants to testify "regarding Prolene, the proprietary blend of polypropylene used in Ethicon's devices indicated for the treatment of pelvic organ prolapse, including Prolift." (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Thames, at 1–2.) The Plaintiff seeks to exclude two areas of Dr. Thames' potential testimony. First, the Plaintiff argues that Dr. Thames should not be permitted to provide "opinions with respect to Ethicon's compliance with design control and risk management standards." (Pl.'s Mot. to Exclude Dr. Thames, at 5.) However, the Plaintiff does not identify specific opinions on this topic from Dr. Thames' report, and the Defendants argue that this challenge should be denied as moot because those opinions do not exist. (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Thames, at 3–4.) The Plaintiff does not address these arguments in her reply brief. As a result, the Court denies her motion as to design control and risk management standards as moot. Second, the Plaintiff seeks to exclude Dr. Thames' testimony regarding the Prolift's alleged *in vivo* degradation that conflicts with the testimony of Ethicon's corporate witness. (Pl.'s Mot. to

Exclude Dr. Thames, at 7.) In her view, because Dr. Thames' "opinions concerning Prolene's propensity to degrade wholly contradict the testimony of Ethicon's corporate representative," those opinions should be excluded. (*Id.* at 10.) But the Plaintiff does not identify any binding precedent for treating the opinions of corporate representatives as equivalent to judicial admissions. Instead, the Plaintiff cites various district court opinions supporting such a rule. (*Id.* at 7–10; Pl.'s Reply Br. in Supp. of Pl.'s Mot. to Exclude Dr. Thames, at 2–3.) The Court finds that no such rule exists in the Eleventh Circuit, and it will not create one here. If Dr. Thames' testimony differs from that of the corporate representative, the Plaintiff can seek to impeach the witness' credibility or seek discovery sanctions for failure to adequately prepare the corporate representative. *See, e.g.*, *Federal Deposit Ins. Corp. v. Hutchins*, 2013 WL 12109446, at *6 n.11 (N.D. Ga. Oct. 25, 2013). Thus, the Plaintiff's motion is denied.

iv. Dr. Lowman

Dr. Joye Lowman is a board-certified OB/GYN with a subspecialty in female pelvic medicine and reconstructive surgery. (Dr. Lowman General Report, at 1.) She has performed over 2800 prolapse surgeries, 150 of which have utilized the Prolift device. (*Id.* at 2.) The Defendants are offering Dr. Lowman as both a general and case-specific expert here, and Judge Goodwin previously issued a narrow ruling on her general opinions, which this Court adopts. *See In re: Ethicon, Inc.*, 2016 WL 4962342 (S.D. W. Va. Aug. 25, 2016).

In that order, Judge Goodwin reserved ruling on whether to exclude Dr. Lowman's testimony regarding "an encounter with a colleague whose patient died during an abdominal sacral colpopexy." *Id.* at *3. The Defendants claim that this specific anecdote will not be offered at trial. (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Lowman, at 11.) Accordingly, the Plaintiff's motion is denied as moot as to this issue.

In her Motion, the Plaintiff raises several new challenges to Dr. Lowman's proposed testimony. First, the Plaintiff asks this Court to exclude Dr. Lowman's testimony that Dr. Tackitt, the Plaintiff's surgeon, did not rely on the information for use during Plaintiff's treatment. (Pl.'s Mot. to Exclude Dr. Lowman, at 4–7.) In her view, Dr. Lowman lacks a reliable methodology for opining that Dr. Tackitt did not rely on the information for uses, especially in light of Dr. Tackitt's testimony that he did rely on the information for uses. (*Id.* at 5–7.) In response, the Defendants seek to clarify the scope of Dr. Lowman's testimony on this topic, claiming that Dr. Lowman will testify that "she believes Dr. Tackitt did not rely solely on the Prolift [information for use] because he used a surgical technique that was not outlined in the [information for use]." (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Lowman, at 5.) To the extent Dr. Lowman's testimony is limited in the manner described by the Defendants—that Dr. Tackitt utilized a surgical procedure in the Plaintiff's case that was not included in the information for uses—the Plaintiff's Motion is denied. Dr. Lowman has sufficient experience to provide relevant and

reliable testimony about the occurrence of a surgical procedure and whether that procedure is included in an information for use. Any further testimony regarding the extent of Dr. Tackitt's reliance, or lack thereof, on the information for uses shall be excluded. This reasoning aligns with the MDL court's rulings allowing experts to testify not to the adequacy of the information for use but rather about the known risks of these procedures and whether the information for uses describe those risks.[4]

Second, the Plaintiff challenges Dr. Lowman's case-specific causation opinion, arguing that she failed to perform a proper and reliable differential diagnosis. (Pl.'s Mot. to Exclude Dr. Lowman at 7–11.) In particular, the Plaintiff's argues that Dr. Lowman's failure to rule out her Prolift surgery as a cause of her symptoms renders her opinion unreliable. (*Id.* at 11.) In response, the Defendants claim that the Plaintiff misunderstands their burden here, and that Dr. Lowman need not conduct a differential diagnosis at all. (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Lowman, at 7.) According to the Defendants, defense experts must merely raise plausible potential causes that cast doubt on the Plaintiff's experts. (*Id.*) Further, the Defendants claim the MDL Court has issued rulings to this effect in other cases from this MDL. (*Id.*,

[4] The Plaintiff seeks the exclusion of Dr. Lowman's testimony as to the adequacy of the information for uses, and the Defendants claim that Dr. Lowman will not offer such testimony. (Pl.'s Mot. to Exclude Dr. Lowman, at 14–15; Defs.' Br. in Opp'n to Pl.'s Mot to Exclude Dr. Lowman, at 2.) As such, the Plaintiff's Motion is denied as moot as to this issue.

Ex. 3, at 4–5.) The Court finds the Defendants' argument persuasive. The Defendants have no burden to establish causation here. As such, the defense experts are "tasked with giving testimony that affects the weight and potentially the admissibility of the plaintiffs' specific causation expert." (*Id.*, Ex. 3, at 4.) Testimony from a defense expert based on her clinical experience and knowledge following a review of the relevant materials is sufficiently reliable and relevant to admit here, and after reviewing her Case-Specific Report, the Court finds Dr. Lowman's analysis satisfies this standard. As such, Dr. Lowman's case-specific causation testimony shall be admitted, and the Plaintiff's motions as to this issue is denied.

Finally, the Plaintiff argues that this Court should exclude Dr. Lowman's critical opinions of Dr. Tackitt's surgical technique during the Plaintiff's second pelvic mesh surgery. (Pl.'s Mot. to Exclude Dr. Lowman, at 11–13.) The Plaintiff challenges Dr. Lowman's criticisms because she "could not point to any material whatsoever that provided any reliable basis for her criticism of" Dr. Tackitt's surgical technique while implanting the Pelvitex mesh. (*Id.* at 12.) The Defendants respond by noting that Dr. Lowman's opinion is that Dr. Tackitt's surgical technique, which involved suturing two different mesh products together, was entirely novel and thus could not be supported by literature. (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Lowman, at 9–10.) In reply, the Plaintiff casts Dr. Lowman's opinion regarding Dr. Tackitt's surgical technique "is the epitome of an opinion based on *ipse dixit* . . . ." (Pl.'s

Reply Br. in Supp. of Pl.'s Mot. to Exclude Dr. Lowman, at 6.) But Dr. Lowman's criticisms are not pure *ipse dixit*. In her report, she explains the potential risks of this technique: "Performing the procedure in this manner will place the meshes on excessive tension, which can cause the mesh to bunch of be pulled taught and can lead to pain." (Dr. Lowman's Case-Specific Report, at 43.) As such, there is no significant "analytical gap between the data and the opinion proffered[,]" and such an opinion is admissible based on Dr. Lowman's surgical experience and stated analysis. *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). As such, the Plaintiff's Motion to Exclude Dr. Lowman is denied.

v. Dr. Rosenblatt

Dr. Peter Rosenblatt is a board-certified urologist specializing in Female Pelvic Medicine and Reconstructive Surgery. (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Rosenblatt, at 1–2.) The Plaintiff seeks the exclusion of his testimony on two topics: Dr. Rosenblatt's opinions regarding the safety and efficacy of mesh and testimony regarding the complication rates of patients in his practice. (PL.'s Mot. to Exclude Dr. Rosenblatt, at 4, 11.) However, the Plaintiff brought a nearly identical challenge to Dr. Rosenblatt's safety and efficacy testimony in the course of the MDL proceedings, which Judge Goodwin denied. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL 2327, Doc. 2428, at 4–9; *id.*, Doc. 3553, at 10. The Court adopts that ruling, and the Plaintiff's motion is denied as to this issue. With regards to testimony

regarding the complication rates, the Defendants note that complication rates were not included in Dr. Rosenblatt's report, nor do they intend to ask him about those rates. (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Dr. Rosenblatt, at 9.) Acknowledging this limitation, the Defendants argue that "Dr. Rosenblatt should be allowed to discuss his vast clinical experience with pelvic mesh products, which may include general descriptors of the occurrence of complications or revision procedures in the context of explaining their safety and efficacy." (*Id.* at 9.) Assuming Dr. Rosenblatt does not attempt to quantify the complication rates in his practice in such a way that would lead the jury to believe his estimates are based on anything more than his personal clinical experience, the Plaintiff's Motion is denied. The Court also notes that Dr. Rosenblatt is limited to opinions included in his report, and any testimony outside of those previously offered could be subject to subsequent *Daubert* challenges.

vi. Mr. Ulatowski

Timothy Ulatowski served 36 years at the FDA and is now a consultant on medical device regulations, FDA procedures, and industry best practices. (Ulatowski Report, at 4.) The Defendants have submitted Ulatowski "as an alternative retained expert that the defense would have used in place of one of their Court[-]limited five (5) retained experts, but for Judge Goodwin's ruling that FDA evidence is excluded." (Pl.'s Mot. to Exclude Mr. Ulatowski, Ex. A, at 2.) If Judge Goodwin's previous ruling on FDA evidence "is revisited or

reversed, then Defendants reserve the right to substitute Mr. Ulatowski in as a retained expert." (*Id.*) The Court finds no reason or occasion to revisit Judge Goodwin's previous rulings on FDA evidence. The Defendants argue that "[u]nless and until this Court allows FDA evidence, . . . it is premature to rule on Plaintiff's challenges to Mr. Ulatowski." (Defs.' Br. in Opp'n to Pl.'s Mot. to Exclude Mr. Ulatowski, at 3.) However, to the extent Ulatowski's proposed testimony exclusively relates to matters involving the FDA evidence, Judge Goodwin's previous rulings on the matter require this Court to grant the motion. Any concerns about improper arguments by the Plaintiff requiring a rebuttal from Mr. Ulatowski can be settled by motions in limine. *See Williams*, 2021 WL 1087808, at *4 n.5 (reaching the same conclusion).

IV. Conclusion

For the reasons set forth above, the Court rules as follows:

- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Sepulveda-Toro [Doc. 52] is DENIED.
- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Schlafstein [Doc. 53] is DENIED.
- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Thames [Doc. 54] is DENIED.
- The Plaintiff's Unopposed Motion for Extension of Time [Doc. 72] is GRANTED.
- The Defendants' Motion to Exclude Certain Case Specific Opinions of Dr. Fitzgerald [Doc. 55] is GRANTED.

- The Defendants' Motion to Limit the Expert Opinions of Dr. Elliott [Doc. 56] is GRANTED in part and DENIED in part.

- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Lowman [Doc. 58] is DENIED.

- The Plaintiff's Motion to Exclude Certain Opinions of Dr. Rosenblatt [Doc. 59] is DENIED.

- The Plaintiff's Motion to Exclude Timothy Ulatowski [Doc. 60] is GRANTED.

- The Defendants' Motion to Exclude the Case-Specific Opinions of Dr. Miklos [Doc. 61] is GRANTED.

- The Defendants' Motion to Exclude the Case-Specific Opinions of Dr. Zipper [Doc. 89] is DENIED.

- The Defendants' Motion to Exclude Certain Opinions and Testimony of Prof. Dr. Uwe Klinge [Doc. 90] is GRANTED in part and DENIED in part.

SO ORDERED, this 12th day of January, 2022.

Thomas W. Thrash

THOMAS W. THRASH, JR.
United States District Judge